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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KODA & ANDROLIA  
2029 CENTURY PARK EAST  
SUITE 3850  
LOS ANGELES, CA 90067-3024

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/07/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/284,935

Applicant(s)

Takebe et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 9, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, and 7 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 12/21/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/284,935 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 2, 4, 5 and 7 as amended (Paper No. 17 filed 12/21/2001) are pending and under examination.

Claims 3, 6 and 8 were canceled by applicants in the Paper No. 13 filed 4/17/2001.

### ***Claim Rejections - 35 U.S.C. § 112***

#### ***Indefinite***

Claims 1, 2, 4, 5 and 7 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 5 are indefinite with regard to several concepts related to the claimed terms "koji", "solid form", "grains", "50% by weight of water", "beneficial microorganisms" and "phytic acid".

What is a "koji" as intended? Is it a fermentate of unknown constitution? Is it sake or miso or moromi? Is it a microbial culture? What characteristic is intended for the claimed "koji" or "koji preparation resultant"? Further, the fact that the "koji" characteristic is uncertain renders the claimed term "koji mold" to be indefinite because the "koji mold" which is claimed is not a

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pure fungal culture belonging to *Aspergillus* and it not a particular fungal strain with the accession number of a culture collection with IDA status but some starter of unknown constitution and of uncertain viability which is locally produced by traditional businesses. The nature and components of the claimed product or material is uncertain as claimed.

With respect to the term "grains" it is noted that while applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "grains" in the claimed invention is used to mean "soybeans," (for example: see specification page 1, line or page 17, line 9 or test 1), while the accepted meaning for a grain is a "seed produced by a cereal grass" but not by a soy plant {see Webster's Dictionary}.

What is "solid form" grains? Are the solid grains dry? What is a moisture content of "solid form" grains? Are grains pretreated or precooked? Whether or not are "solid form" grains present in an aqueous solution? Further, the limitation directed to addition of "A maximum of 50% by weight of water" appears to create more confusion in the claims because the water content of "koji mold", "solid from" grains and "koji preparation resultant" is uncertain. It is also uncertain whether the amount of "maximum of 50% by weight of water" are intended for hydrolysis and phytic acid removal or for propagation of "beneficial microorganisms". From the applicants' disclosure (see specification page 12, line 24) it does not appear that the particular amount of "50%" is the essential element because it is suggested as an example rather than the requirement. Further, the claimed range such as "a maximum of 50% by weight of water" is not

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limited by any minimum amount and, thus, it is uncertain whether any addition of water is required by the claimed invention.

With respect to the step of removing phytic acid from the grains it is uncertain when this event takes place in the claimed process. Does it occur before or after propagation of "beneficial microorganism" (lactic bacteria, for example)? What microorganisms (koji mold or "beneficial" microorganisms) are agents which are intended for removal of phytic acid? Whether or not is a phytic acid an antibacterial (antimicrobial) agent which might inhibit propagation and or viability of "beneficial" microorganisms? What is "predetermined" amount of phytic acid? How much is removed? How is this amount predetermined? Whether or not is the type of "grains" taken into consideration in predetermination of amounts which are intended to be removed?

With regard to "beneficial microorganisms" it is uncertain what microbial species are intended, what is the source of "beneficial microorganism" and whether the microorganisms are inherently present within starting "grains" or "koji mold" or whether the microorganisms are added to "koji preparation resultant" when koji preparation is completed and phytic acid is removed. Is there the difference and what is between "koji mold" and "beneficial microorganisms"? Koji mold appears to be beneficial by the virtue of being used in koji preparation which "sustain the health of living beings" (see claims 1 and 5, for example). Thus, the claimed invention does not require addition of microorganisms distinct or different from "koji mold". The composition (material or product) of claim 2 is not limited to incorporation of lactic

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bacteria as “beneficial” microorganisms because lactic bacteria is intended to be within “the intestine of animals” as claimed.

Claims 4 and 7 are confusing and appear to have improper Markush group because some “beneficial” microorganisms are limited by common names (lactic acid bacteria and bifidobacteria) and some are limited by Latin taxonomic names (*Eumycetes*) wherein the difference between lactic bacteria and bifidobacteria is uncertain as claimed and as intended and wherein *Eumycetes* appear to be “koji mold” or *Aspergillus* since *Eumycetes* are fungal cultures (see Ainsworth & Bibsy’s Dictionary of the Fungi at page 158).

Claim 2 remains indefinite with respect to the term “resistant” starch because it is uncertain what product is intended and whether the claimed “resistant” is the essential element for the present invention. Would be any difference between the claimed resistant starch and starch as inert absorbent in therapeutic composition? How to select a “resistant” starch which is intended? For example: Merck Index (page 1502) teaches that generic starch is comparatively resistant. Applicants argue that “resistant starch” is a well known term (Preliminary amendment filed 1/09/2002 page 3) and provide some definitions of starch being resistant to degradation by enzymes wherein the interpretation which is argued does not appear to be different from the Merck’s definitions of a generic starch. Thus, the “resistant” starch as claimed is either indefinite or the resistance of starch which is claimed is not an essential element.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37CFR 3.73(b).

Claims 1, 2 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161 [D].

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a product or material with health-promoting effects obtained by hydrolysis of grains or crops such as soybeans with koji molds in the presence of beneficial microorganisms including lactic bacteria. The limitations such as presence of at least some amounts of water during preparation of the claimed product/material and removal of phytic acid which are claimed in the instant application are inherently present in the claimed product of US 6,303,161 because US 6,303,161 clearly teaches that water was added during koji preparation and phytic acid was removed from the product of the invention of US '161 (for example: see at col.7, lines 44-55; col. 12, line 50-52; col.14, line 25). Further, the claimed product US'161 is required "to be formed so as to be absorbed by digestive tract" (see claim 9, for example) or it

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requires incorporation of therapeutically suitable absorbent such as, for example: starch which is required by the product of the instant claims. Accordingly, the claimed products are obvious variants. Thus, the inventions as claimed are co-extensive.

Claims 5 and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 of copending Application No. 09/284,935 which is divisional of Application No. 09/194,657 now US 6,393,161 [D]. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to a process for preparing a product or a material with health-promoting effects obtained by hydrolysis of grains or crops such as soybeans with koji molds in the presence of beneficial microorganisms including lactic bacteria for the reasons as explained above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 4, 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,885,632 [B].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid wherein hydrolysis of the resultant is obtained by action of beneficial microorganisms contained in the resultant. The intended effects of the claimed product are health-promoting effects related to propagation of beneficial microorganisms. Some claims are further limited to beneficial microorganisms such as *Eumycetes* or fungal cultures or koji molds.

5,885,632 [B] teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid (fig. 1; col. 4, lines 35-45 or lines 52-57) wherein hydrolysis of the resultant is obtained by action of beneficial microorganisms contained in the resultant such as *Eumycetes* or fungal cultures or various koji molds (col. 6, lines 43-45). The effects of the US' 632 product are health-promoting effects related to propagation of beneficial microorganisms and/or other health-promoting effects such as carcinopreventive (see abstract). The amount of water which is added and/or present during hydrolysis is no more than 50 % or 40% (col. 6, line 25) as required by the presently

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claimed invention. Thus, the disclosure of US' 632 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Claims 1, 4, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,308,284 [A] in the light of evidence provided by teaching of US 5,885,632 [B] or JP 7-23725 [N].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as rice or soybeans with koji mold to create a koji preparation resultant, adding water and beneficial microorganisms to the resultant, and removing phytic acid. The intended effects of the claimed product are health-promoting effects related to propagation of beneficial microorganisms. Some claims are further limited to beneficial microorganisms such as lactic acid bacteria and bifidobacteria. The amount of water which is added is either uncertain or non-essential for the reasons as explained above.

US 4,308,284 [A] clearly teaches a process and a product obtained by the process comprising steps of inoculating grains or crops (soybeans or rice or wheat) with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria (abstract; col. 7, lines 5-30; col.3, lines 61-64; col.4, lines 44-46; col.5, line 21). The step of removing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition-obtained-by-method of the cited patent '284 in the light of evidence as

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taught by US 5,885,632 [B] or JP 7-23725 [N]. For example: the teaching of US 5,885,632 [B] demonstrates that koji molds have high phytase which are enzymes decomposing phytic acid and phytic acid is removed in the presence of added water during koji mold hydrolysis (see US'632 col. 9, lines 15 and col.8, lines 60-67). And the presently claimed method and composition-obtained-by-method are encompassing the use of identical koji molds, the use of identical grains/resultants and the use of additional water as it is taught by US 5,885,632. Therefore, the step of removing phytic acid appears to be inherently present in the method and composition-obtained-by-methods are directed to the use of identical koji molds and grains as claimed and as disclosed. The teaching of JP 7-23725 [N] is similar to US 5,885,632 [B] (see English abstract). Thus, the disclosure of US 4,308,284 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Claims 1, 4, 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,965,178 [E] in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains with koji mold to create a koji preparation resultant, adding water to the resultant, adding beneficial microorganisms to the resultant, and removing phytic acid. The intended effects of the claimed product are health-promoting effects related to propagation of beneficial microorganisms. Some claims are further limited to beneficial

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microorganisms such as lactic acid bacteria and bifidobacteria. The amount of water which is added is either uncertain or non-essential for the reasons as explained above.

US 5,965,178 [E] clearly teaches a process and a product obtained by the process comprising steps of inoculating grains or crops such as soybeans or rice or wheat (col. 2, line 57) with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria (abstract; col. 4, example 1, line 31 and lines 47-51). The cited US '178 teaches a the use of a large variety of beneficial microorganisms (col. 2, lines 40-50) and the use of "solid state" for koji preparation (col. 2, line 63) as appears to be encompassed by the presently claimed invention. The step of removing phytic acid from the grains is inherently present in the method/composition-obtained-by-method of the cited patent '178 in the light of evidence as taught by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained above. Thus, the disclosure of US' 178 [E] appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,329,370 [F] in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating solid form of grains with koji mold to create a koji preparation resultant, adding water and beneficial microorganisms to the resultant, and removing phytic acid. The intended effects of the claimed product are health-promoting effects related to

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propagation of beneficial microorganisms. The amount of water which is added is either uncertain or non-essential for the reasons as explained above.

US 4,329,370 [F] teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating solid form of grains with koji mold to create a koji preparation resultant, adding water or suspension with beneficial bacteria to the resultant (col. 8, lines 22-25), and removing phytic acid. The step of removing phytic acid from the grains is inherently present in the method/composition-obtained-by-method of the cited patent '370 in the light of evidence provided by US 5,885,632 [B] or JP 7-23725 [N] for the reasons as explained above. The amount of water which is added is either uncertain or non-essential for the reasons as explained above. Moreover, the amount of water which is present during hydrolysis is no more than 50 % or 44.5% as required by the claimed invention and as disclosed by the cited patent (col. 8, line 18). The intended effects of the claimed product are health-promoting effects related to propagation of beneficial microorganisms. Thus, the disclosure of US' 370 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed.

### ***Claim Rejections - 35 U.S.C. § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1, 2, 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885, 632 [B] or US 4,308,284 [A] or US 5,965,178 [E] or US 4,329,370 [F] in the light of evidence provided by US 5,885,632 [B] or by JP 7-23725 [N] taken with US 5,118,626 [C], Remington [U], Merck [V] and JP 3-19686 [O].

Claims 1, 4, 5 and 7 as explained above. The claim 2 is further drawn to incorporation of starch into the composition.

The teaching of the cited references US 5,885, 632 [B] or US 4,308,284 [A] or US 5,965,178 [E] or US 4,329,370 [F] and US 5,885,632 [B] or by JP 7-23725 [N] is relied upon as explained above. The cited references are lacking a particular disclosure related to incorporation of starch into a final fermentation product.

The secondary references Remington [U] or Merck [V] teach starch as an absorbent suitable for any pharmaceutical preparations or food or edible product.

Additional secondary reference JP- 3-19686 [O] is relied upon to demonstrate that a material obtained from grains fermented with koji molds is useful for promoting grow of beneficial lactic bacteria or bifidobacteria belonging to the genus of *Bifidobacterium*.

Additional secondary reference US 5,118,626 [C] is relied upon for the disclosure of the teaching that starch is progressively converted by microbial action of koji molds and lactic bacteria (col. 1, lines 18-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was incorporate starch into composition obtained by fermenting grains with

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koji molds and beneficial lactic bacteria with a reasonable expectation of success in obtaining product suitable as therapeutical or edible compositions intended for promoting growth of lactic bacteria and health of living beings because starch is suitable for any pharmaceutical preparations or food or edible product and because starch is a known nutrient for microorganisms including koji molds and lactic bacteria. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

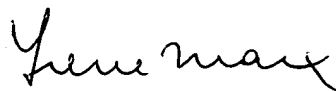
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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February 4, 2002.

  
IRENE MARX  
PRIMARY EXAMINER